

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images,

please do not report the images to the
Image Problem Mailbox.

THIS PAGE BLANK (USPTO)

PCT

EP 0198915
 WORLD INTELLECTUAL PROPERTY ORGANIZATION
 International Bureau

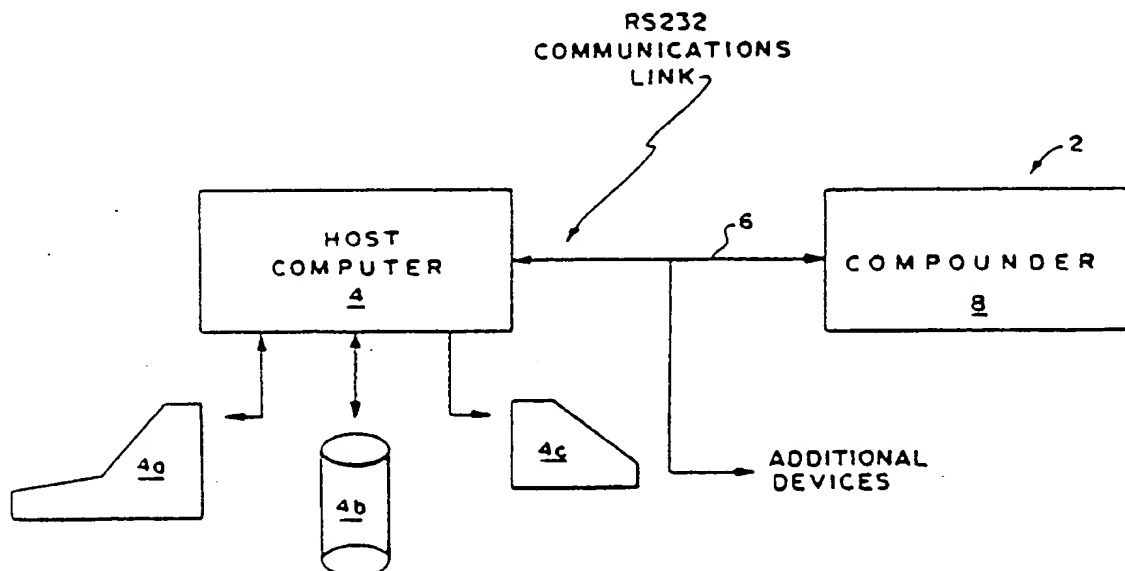


57

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : B67D 5/14, G06F 15/42, 15/46	A1	(11) International Publication Number: WO 86/ 02625 (43) International Publication Date: 9 May 1986 (09.05.86)
(21) International Application Number: PCT/US85/02025 (22) International Filing Date: 18 October 1985 (18.10.85) (31) Priority Application Number: 665,268 (32) Priority Date: 26 October 1984 (26.10.84) (33) Priority Country: US (71) Applicant: BAXTER TRAVENOL LABORATORIES, INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US). (72) Inventors: FIGLER, Alan, Anthony ; 3709 Live Oak road, Crystal Lake, IL 60014 (US). DIGIANFILIPPO, Alejandro ; 5806 Dhadowood Drive, Crystal Lake, IL 60014 (US).	(74) Agents: PIERCE, Kay, H. et al.; One Baxter parkway, Deerfield, IL 60015 (US). (81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published With international search report.	

(54) Title: COMPOUNDING SYSTEM



(57) Abstract

A fast, efficient and precise method and apparatus for compounding a large number of solutions for use in hyperalimentation therapy. The apparatus includes a host computer (4) which maintains a data base of prescriptions to be compounded, and a high speed compounding apparatus (8) connected to the host computer (4) for compounding mixtures of base solutions in response to information supplied by the host computer from the prescription data base. Information can be entered concerning patients or prescriptions through a display into the host computer data base. The host computer also includes provisions for a library of prestored standard prescriptions which can be recalled and associated with a given patient. A group of prescriptions to be compounded is first sorted in accordance with the types of specified base solutions and optionally sorted again based on the concentration of base solutions. The prescription information is transmitted to the compounding apparatus in sorted order thereby minimizing the required number of containers of base solution.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GA	Gabon	MR	Mauritania
AU	Australia	GB	United Kingdom	MW	Malawi
BB	Barbados	HU	Hungary	NL	Netherlands
BE	Belgium	IT	Italy	NO	Norway
BG	Bulgaria	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali		
FR	France				

-1-

COMPOUNDING SYSTEM

BACKGROUND OF THE INVENTION

The present invention pertains to a process and apparatus for precisely and rapidly mixing base solutions. More particularly, it pertains to such a process and apparatus especially useful for the compounding of hyperalimentation solutions.

Hyperalimentation therapy is the intravenous feeding of, for example, a protein-carbohydrate mixture to a patient. It is used primarily to meet the patient's protein and caloric requirements which are unable to be satisfied by oral feeding. The protein may be in the form of free-amino acids or protein hydrolysate, and the carbohydrate commonly is dextrose. In addition to the protein and carbohydrate, vitamins (water-soluble and fat-soluble) and electrolytes also can be supplied in this therapy.

Each of these parenteral ingredients and the combination thereof are particularly susceptible to the growth of deleterious organisms and it is desirable that they be administered to the patient in a sterile condition. Thus, because these protein and carbohydrate solutions cannot be pre-compounded by the manufacturer, but must be combined at the time of their use, their compounding must be performed under sterile conditions to avoid organism growth.

A known apparatus and process for compounding hyperalimentation solutions utilizes a solution transfer system including a receiving container and a Y-transfer set. The Y-transfer set includes two separate tubes, each having an end attached to a common juncture by which solutions delivered through the tubes will pass through the juncture into the receiving container. The other end of one tube of the set is attached to the protein holding container and of

-2-

the other tube of the set to the carbohydrate holding container. The desired volume of each solution being transferred to the container is controlled by a clamp placed on each tube. The solutions may be allowed to flow into the receiving container by gravity flow. However, it has been found to be useful to transfer the solutions under the influence of a vacuum applied to the receiving container. When the receiving container is a flexible plastic container, the vacuum is created in a vacuum chamber into which the container is placed.

It has been known in the past that to ensure sterility during the compounding of hyperalimentation solutions, compounding should be performed under a laminar flow hood. Laminar flow hoods are used for reducing the risk of airborne contamination of such solutions. These units operate by taking room air and passing it through a pre-filter to remove gross contaminants, such as dust and lint. The air is then compressed and channeled through a bacterial retentive filter in the hood in a laminar flow fashion. The purified air flows out over the entire work surface of the hood in parallel lines at a uniform velocity. The bacterial retentive type of filter is designed to remove all bacteria from the air being filtered.

Compounding under a laminar flow hood aids in preventing airborne contamination, but it is relatively cumbersome and expensive and would not be useful for eliminating any other source of contamination, such as contamination caused by handling. When using a hood the operator may inadvertently perform the work at the end or outside of the hood and not within the recommended space, at least six (6) inches within the hood, which insures the benefits of the air being purified. Time must be taken and care must be exercised to maintain a direct open path between the filter and the compounding area. Solution bottles and other non-sterile objects cannot be placed at the back of the hood

-3-

work area next to the filter because these objects could contaminate everything downstream and disrupt the laminar flow pattern of the purified air. Also, in using a laminar flow hood, it is necessary routinely to clean the work surface of the hood before any compounding is performed.

Other manually controlled devices are known from the prior art for mixing base solutions. These devices use peristaltic pumps to transfer specified quantities of solution to transfer specified quantities of solution to a container. The desired quantities of solution to be transferred are determined in advance and entered by hand into the control unit of the pumping apparatus. The pumping apparatus then delivers the desired quantity of solutions to the mixture container. Such an apparatus and method are disclosed in U.S. Patent Application Serial Nos. 391,758 and 391,759, both filed on June 24, 1982 and entitled respectively "Flow Monitoring Method and Apparatus" now United States Patent No. 4,467,844 and "High Speed Bulk Compounder" now United States Patent No. 4,513,796. Said applications have been assigned to the assignee of the present invention.

In order to use the devices and methods disclosed in the above identified applications it is usually necessary to manually translate a prescription from a short-hand designation to a set of parameters that includes the type, concentration and volume of each of the base solutions to be mixed. After the base solutions have been mixed, additives such as trace elements or vitamins can be added to make the final mixture.

The manual translation to a set of volumetric parameters is both time consuming and expensive as the process is usually carried out by a pharmacist. In addition, errors can occur during the calculation process. Further, the manual calculations to a certain extent are only approximations in that the small volumetric additions of the additives are often not taken into consideration.

-4-

If a group of prescriptions is to be compounded, once the manual translations have been completed, the order in which the members of the group are compounded becomes important. Compounders of the type disclosed in the above
5 two applications are designed such that a container of base solution that has been partly emptied cannot be removed from the compounder and later reinserted. The containers of base solution which include dextrose, lipids and sterile water are expensive. It is therefore desirable to completely
10 empty each container before removing it from the compounder.

To minimize over-all cost it would be desirable to optimize the compounding of a group of prescriptions by minimizing the needed number of containers of base solution. This requires a careful ordering of all prescriptions to be
15 prepared at one time. Finally, labels must be prepared to identify each mixed prescription.

The process and method of the present invention provide for the translation from a prescription name to a detailed set of parameters without manual calculations. In
20 addition, the compounding of a group of prescriptions can be optimized by the present invention by sorting the prescriptions in accordance with the type of base solution and then compounding them in the sorted order.

SUMMARY OF THE INVENTION

In accordance with the present invention a system and a method are provided for compounding a plurality of selected mixtures from one or more base solutions. The system includes a storage device for storing sets of parameters for a group of mixtures which are to be compounded from the base solutions. A compounder is electrically connected to the storage device, and in combination with the storage device, compounds a selected mixture on receiving a set of parameters which define the base solutions to be used and the amounts thereof. The storage device can be part of a host computer system which transfers information to, and receives information from the compounder by means of a communications link.

A program in the host computer maintains a data base of patient information. Associated with each patient entry are one or more mixtures for the patient which can be compounded from the base solutions. Both patient information and a set of parameters to define a mixture for the patient may be entered through a display and data entry terminal. The parameters for the base solutions of a mixture may be entered in the form of the volumes of the desired base solutions, the percentages of the total volume of the final mixture that each base solution represents, or as a nutritional contribution of each base solution to the final mixture. Each of the three forms of specifying the base solutions of a given mixture is essentially equivalent to the other two and the other two may be derived therefrom.

Additionally, the system provides a library function whereby a group of standard mixtures may be prestored as sets of parameters with a given name and called up or associated with a selected patient.

-6-

A set of parameters which defines a mixture for a given patient, referred to as a bag, is placed in one or more time slots or queues in the host computer to provide for one or more dosages to be given to a patient during a
5 twenty-four hour period. Each queue corresponds to a given time interval within a twenty-four hour day.

The host computer provides facilities for a pharmacist to review each set of parameters, or bags, in a given queue and to authorize the compounding, or creation of the
10 base solution mixture, during an initial part of each time period or shift. The host computer then sorts all of the authorized bags based on the specified base solutions. Compounding the mixtures in their sorted order results in a minimal number of containers of the base solutions being
15 necessary. This results in minimal overall cost.

An important advantage of the present invention that results from sorting the authorized bags is the minimization of changes of tubing in the compounding apparatus. This unexpected result provides for lower overall cost. A
20 further advantage is due to the ability of the host computer to take into account the small volumes of the additives when calculating the desired volumes of base solution.

Once a group of authorized bags has been sorted the system prints a set of labels corresponding to the
25 sorted order of the group.

The types of base solutions and quantities for each authorized set of parameters, or bag, for a given time slot or queue are then presented in sorted order to the compounding apparatus. The compounding apparatus requires
30 that the volumes of the base solutions be specified. Hence, volumetric information for each authorized bag is transmitted to the compounding apparatus in the sorted order. During the compounding process the set of preprinted labels provides a cross-check to ensure that the correct base

-7-

solutions, amounts, and concentrations are provided for each mixed bag.

5 A log which keeps track of each operation is also created by the host computer. The log may be in the form of a printed copy or a disk file or both. The logged operations include entering new patient information, entering a new set of parameters, defining a bag, altering a set of parameters, and compounding one or more bags of solution.

10 Provision is made in the compounding apparatus for operator verification of the type, quantity and concentration of base solution to be compounded into the final mixture. Additionally, provision is made at the compounding apparatus to provide for entry of a patient identification number so that a bag can be prepared out of order should the need
15 arise. Provision is also made in the host computer to inform the compounding apparatus of any change in the type or concentration of solution being used to enable the host computer to monitor the current base solutions being used.

20 The method of the present invention includes storing parameters for one or more mixtures; transferring base solution information from a storing location to a compounding location and compounding the desired mixtures.

-8-

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an overall block diagram of a system in accordance with the present invention.

5 Figure 2 is a perspective view of a compounding apparatus configured in accordance with the present invention.

Figure 3 is a front view of the control panel of the compounding apparatus configured in accordance with the present invention.

10 Figure 4 is a schematic block diagram of the compounding apparatus configured in accordance with the present invention.

Figure 5 is an overall flow diagram of the operation of the present invention.

-9-

DETAILED DESCRIPTION

Referring now to Figure 1, a system 2 embodying the present invention is illustrated. The system 2 includes a host computer 4 having at least one display and data entry terminal 4a which may include a cathode ray tube and keyboard or the like, a disk drive 4b and a printer 4c connected thereto. The host computer 4 can be selected from a variety of small computers including the IBM PC and PCXT or a comparable system. If desired, a larger computer system such as a Digital Equipment Corporation VAX could also be used. The computer 4 can be coupled through an RS 232 communications link 6 to a compounder 8. Additional compounders or other devices may be coupled through communications links to the host computer 4. The communications link 6 provides bidirectional communication between the host computer 4 and compounder 8. Alternately, the computer 4 could be hardwired to the compounder 8.

The host computer stores on its disk drive 4b programs for data input, for generating commands to drive the compounder 8, for handling input of authorizations for compounding prescriptions, for scheduling and sorting, for communications, for report generation and for audit trail generation. The host computer 4 also stores on its disk drive 4b patient information as well as sets of parameters of mixtures or prescriptions to be prepared for patients. A set of parameters corresponds to a prescription and might be input to the system 2 with only a name of a known standard mixture to be prepared for a patient.

Figure 2 is a perspective view of a portion of the mechanical apparatus of the compounder 8. The compounder 8 includes a framework 10 upon which is hung a plurality of base solution containers 12, 14 and 16. Typical base solutions include amino acids, dextrose, and lipids, all of

-10-

which are available in different concentrations, as well as sterile water. Base solutions are sometimes referred to as base component solutions. An output bag 18 is supported on the framework 10 and receives solutions from the containers 12 through 16 in quantities determined by the host computer 4 and the information stored therein. Base solutions are transferred from the containers 12 through 16 by means of peristaltic pumps 20 through 24. A control panel 26 is available to provide displays of information from the host computer 4 as well as to provide a means for operator input of control and feedback information concerning the status of the compounder 8. A housing 30 supports the framework 10 as well as the pumps 20 through 24. A front cover 34 covers the pumps.

15 The supply container 12 is coupled with the collection container 18 by flexible tubing 36. The flexible tubing 36 enters the housing 30 at inlet 38 and is placed around rollers (not shown) of the peristaltic pump 20. The flexible tubing 36 can be connected to another portion of flexible tubing (not shown) for placement around the rollers of the peristaltic pump. The tubing 36 then exits the housing 30 at outlet 40 and enters a junction block 42 coupled to the collection container 18. The junction block 42 provides a channel through which solutions being pumped through a flexible tube can flow to the collection bag 18.

25 The peristaltic pump 20, in operation, transfers the sterile solution in the supply container 12 to the collection bag 18 by movement of the rollers (not shown) in the pump 20. This movement causes a compression of the walls of the flexible tubing 36 forcing the solution therein forward in a capillary type action. Retainers 44 and 46 are placed around the flexible tubing 36 at its entrance to and exit from the housing 30 to keep the tubing 36 in place during the operation of the pump 20.

-11-

The supply container 14 is coupled with the collection bag 18 by the flexible tubing 48. The sterile solution in the container 14 is delivered to the bag 18 by the peristaltic pump 22 in a similar fashion to the fluid delivered from container 12 caused by the pump 20. The flexible tubing 48 also has retainers 50 and 52 placed in a similar manner to the retainers 44 and 46 of the flexible tubing 36. The supply container 16 is coupled with the collection bag 18 by flexible tubing 54 with the peristaltic pump 24 therebetween. The tubing 54 has retainers 56 and 58 identical in placement and purpose to the retainers 44, 46, 50 and 52.

A manually operable compounder and method of operating same is disclosed in United States Patent Application Serial No. 391,758, filed June 24, 1982, now allowed as U.S. Patent No. 4,467,844, entitled "Flow Monitoring Method and Apparatus" and assigned to the assignee of the present invention. A manually operated compounder is also disclosed in United States Patent Application Serial No. 391,759 filed June 24, 1982, now allowed as U.S. Patent No. 4,513,796, entitled "High Speed Bulk Compounder" assigned to the assignee of the present invention. The above two patents discuss the theory of operation of manually controlled compounders similar mechanically to the compounder 8. The disclosures of said two patents are incorporated herein by reference.

Figure 3 is a view of the control panel 60 of the control unit 26. Panel 60 includes a 16 key keyboard 62 which is manually operable having digits 0 through 9, a recall key 64 a clear keyboard key 66 and four keys 68 labeled AI, for Auto I/D, MI, for Manual I/D, ST for standard manual operation and V.I, for Verify I/D. The key switches 68 are used by the operator when the compounder 8 is under control of the host computer 4. Each of the supply containers 12 through 16 is associated with a base solution volume to be delivered which is displayed at various times

-12-

on the displays 70 through 74. Additionally, patient I/D codes can be displayed thereon. A set of switches 78 through 82 provides for manual entry of volumic parameters of base solutions that are then displayed on display 70 through 74 when the compounder 8 is operating in a manual mode. A specific gravity display 84 through 88 and a set of specific gravity entry switches 90 through 94 are also used for entering respective specific gravity information when operating in a manual mode. A total delivered display 102 provides an indicia of the quantity of solution delivered to the output bag 18 during a given compounding operation. Alternately when operating in connection with the host computer 4 a bag identification number is displayed at times in display unit 102. Lights 96, and 104 through 108 provide manually viewable indicia for the operator of the status of the compounder 8 and can be sensed by the host computer 4 when running in the automatic mode.

Figure 4 is a schematic block diagram of the electronics of the compounder 8. The compounder 8 includes a control unit 110 which can be a Motorola 6802 microcomputer chip, read only memory 112 (ROM), random access memory 114 (RAM), a communications port 116 an analog to digital converter 118 and a load cell 120. Outputs from the control unit 110 drive the pumps 20 through 24. The ROM memory 112 of Figure 4 includes a control program for operating the compounder 8 in connection with the host computer 4.

FIG. 5 is an overall flow diagram showing the operation of the system 2. In an initial step 130, patient information is entered into the host computer via the display and data entry terminal 4a and stored by the disc drive 4b. Typical patient information includes a patient identification number and billing code, the patient's name, room number and physician, and the patient's age, weight and height. Information as to the patient's diagnosis, disease state and allergies is also included. In addition, a log

-13-

identifying the date and time of data entry and the person making the entries is maintained by the host computer.

Once the patient information has been entered, the next step is to enter a prescription to be compounded. The prescription is entered into one or more available queues. For example, four compounding queues can be used and allocated to six hour intervals during a twenty-four hour day. New patient information, as well as prescription information, is stored by the disc drive 4b for subsequent use.

In step 132, the prescription to be entered, i.e., the mixture to be compounded in bag 18, is entered into the host computer where it is stored on the disc drive for subsequent use. The prescription may be entered in any way of a number of alternative forms. For example, the prescription may be specified in terms of the volume and concentration of each base solution which is to make up the bag 18. For example, a typical prescription could be specified as: 100 ml amino acid at 10%; 100 ml dextrose at 50%; and 100 ml lipid at 10% where amino acid, dextrose and lipid are the base solutions which make up the mixture. To complete the prescription, the total volume thereof must also be specified so that the proper amount of water may be added. In the example, if the total volume is specified as 1000 ml, 700 ml of water would be added to provide the desired total volume.

The prescription may also be entered at step 132 in terms of the percent of base solutions which are to make up the final mixture in bag 18 when the total volume of the final bag is also specified. A typical prescription entered in this form may be as follows: 1% amino acid; 5% dextrose; 1% lipid; and a total volume of 1000 ml.

In both of the above examples, the total volumes of the final bag 18 are the same. It can also be seen that the prescriptions themselves are equivalent: 1% amino acid [lipid] x 1000 ml total volume + 10% concentration = 100 ml

-14-

amino acid [lipid] at 10%; 5% dextrose x 1000 ml total volume + 50% concentration = 100 ml dextrose at 50%.

The prescription may also be entered at step 132 by specifying the nutritional contribution in terms of calories of the various base solutions of the final mixture as well as the total volume of the final mixture. For example, a typical prescription entered in this form may be specified as 41 protein calories; 171 dextrose calories; 40 lipid calories; and a total volume of 1000 ml.

A prescription can also be entered by using the name of a presorted mixture and associating it with a given patient. A library of presorted prescriptions is maintained on the disc drive 4b. Each member of the library can be accessed merely by using a shorthand name. The library feature enables a short name to be used to define all of the parameters for a given prescription. The standard parameter values can then be altered if necessary. This ability to refer to standard, presorted mixtures eliminates many of the manual calculations now carried out by pharmacists and provides for a substantial increase in the productivity of the person who would otherwise have to transfer a prescription to a detailed set of parameters. Standard prescriptions can be added to or deleted from the library maintained on the disc drive 4b as needed.

Regardless of the manner in which the prescription is entered into the host computer 4, each entered prescription has associated with it the name of the patient, the patient identification number, a bag number and the infusion rate at which the final compound is to be infused to the patient. The log for identifying when the prescription information was entered and updated and the name of the person making the entries is also maintained.

Additives such as trace elements, vitamins or additional solutions which are to make up the final mixture are also entered to the host computer in step 132. These

-15-

additives form a part of the prescription for a particular patient; however, they are not, in the present embodiment, incorporated into the final mixture until after the bag 18 has been compounded. The additives, such as sodium chloride, sodium acetate, calcium, gluconate, iron, selenium, zinc, multi-vitamin 12, heparin and folic acid are typically added into the medication port of the bag 18 by a syringe after the bag has been compounded.

An operator may input and/or alter any one of the three forms of base solution parameters and the host computer will automatically update the other two forms. Similarly, in the library of prestored sets of parameters, any or all three of the forms of the entered prescription data can be stored for subsequent recall and viewing on the cathode ray tube. Each of the alternative display forms represents a set of parameters associated with a given patient identification number and a given bag number. The bag number refers to the identification number to be applied to the mixture bag 18. Further, the bag number also identifies a given prescription within the data base of the host computer 4.

After a set of parameters for a bag has been defined in one of the available forms in step 132, the host computer 4, in step 134, converts the form of the input set into the alternate equivalent forms available. A given set of parameters for a bag, or a prescription, may be entered into one or more of the available queues which determines how many times during a given twenty-four hour period the prescription or bag is eligible for compounding. Additionally, the host computer 4 also determines how much sterile water needs to be added to the specified base solutions to arrive at the volume ordered. The calculation for water can also take into account the very small volume contributions of the additives which are often ignored when such calculations are manually carried out.

-16-

In the next step 136 as shown in Figure 5, each of the sets of the parameters or members of a given queue is reviewed by a qualified professional, usually a pharmacist, to determine if any changes or corrections need to be made to the defined parameters and also to authorize actual compounding of the mixture in a given time interval. Information for a given set of parameters is not sent to the compounder 8 by the host computer 4 unless compounding of that particular bag or set of parameters has been previously authorized for a given shift or queue. Authorization is carried out by operator intervention through the display and data entry terminal 4a. Absent express authorization, a given set of parameters, or bag, will not be compounded.

After all the prescriptions in a selected queue have been reviewed for authorization, the authorized prescriptions are sorted by the host computer, in a step 138. In sorting the authorized prescriptions, the host computer uses the prescription data in the volumetric quantity form.

The volumetric quantity of each base solution in a particular prescription is first compared to a constant. The constant, e.g., 20, represents the minimum amount of solution (in milliliters) which can be precisely transferred from one of the base solution containers 12, 14, 16 into the final compound bag 18 by the compounder 8. If the volumetric quantity of the base solution is less than the constant, the base solution is not recognized as being present in the prescription. Base solutions having a volumetric quantity equal to or greater than the constant are recognized as being present in the prescription.

Next, the computer 4 selects the three largest volumetric quantities of each prescription and sets the remaining quantities to zero. All but three quantities are set to zero since the compounder 8, in the present embodiment, can compound only three base solution bags 12, 14 and 16 at one time. The base solutions set to zero are added to

-17-

the bag 18 with the additives to form the final mixture. For example, in the prescription 100 ml amino acid; 100 ml dextrose; 100 ml lipid; and 700 ml sterile water, the computer will set the volumetric quantity for lipid to zero. The 100 ml of lipid is then added to the final bag 18 with the nutritional additives after the bag was compounded by the compounder 8..

The computer 4 then compares a predefined list of base solution combinations with the various prescriptions having the up to three non-zero volumetric quantities. The list defines the combinations which can be made from the possible base solutions taking three base solutions at a time. For example, there are four combinations which can be made from the base solutions amino acid, dextrose, lipid and water taking three of them at a time: 1) amino acid, dextrose and water; 2) amino acid, dextrose and lipid; 3) amino acid, lipid and water; and 4) dextrose, lipid and water. As in this example, the list of combinations is arranged such that two of the base solution components in a particular combination are the same as those in the adjacent combination. If there were five possible base solution components, there would be ten possible combinations $[(3 + 2)! + 3! \times 2!]$.

If a combination matches a previously unselected prescription, that prescription is placed in a group of prescriptions associated with that combination. For example, if a prescription calls only for dextrose and amino acid, it will be placed in the first group in the above example. While this prescription could also be placed in the second group in the above example, it will not be since it was already placed with the first.

A second level sort is then performed in step 142 by the computer 4. This sort is made in accordance with the required base solution concentrations contained in the various prescriptions within a group. For example, if in a particular group there were three prescriptions each calling

-18-

for amino acid and dextrose, but two of the prescriptions in the group called for amino acid at 10% concentration while the third prescription called for amino acid at 8.5% concentration, the two formulas having the 10% amino acid concentration would be placed adjacent to each other within the queue. It would also be possible to conduct a third sort based on the size of the needed bag 18 for each set of parameters.

The sorting operations performed on the prescriptions in the selected queue do not alter the prescriptions as they are stored on the disk 4b. Thus, the full prescriptions (including nutritional additives) can be sent to the compounder 8 in sorted order.

The required mixture bags 18 can now be compounded at a minimum cost since the set of authorized bags has been sorted according to the type of base solutions needed. Minimum cost is achieved by making the fewest number of changes to the base solution containers such as 12 through 16 during the compounding process of a large number of mixture bags 18. The containers 12 through 16, as noted above, cannot be placed back in the compounder 8 if it is necessary to remove them before they are empty. As a result, partly empty base solution containers 12 through 16 are thrown away and increase cost. By sorting the authorized sets of parameters, or bags, as described above, the fewest number of base solution containers 12 through 16 will be required. As a result, wasted base solution will be minimized.

As a further advantage, because the system initially sorts in accordance with base component solution families, the need to flush the lines, such as the lines 36, 48, 54 is minimized. This is important in that it minimizes labor on the part of the operator. It further is important in that it reduces the possibility of contamination of the base component solutions. Finally, it is important in that

-19-

with respect to some types of solutions, merely flushing the compounder lines is inadequate. In such cases the entire set of lines 36, 48, 52 as well as block 42 must be disposed of and replaced with a new, sterile set which further contributes to the overall cost. Sorting thus minimizes the need to change sets of lines.

Once the authorized sets of parameters or bags have been sorted in a given queue, a print queue is formed in a step 142 and the host computer 4 prints a sequence of labels on the printer 4c in the same sorted order. The labels printed in the step 142 will be used during the actual compounding process for the purpose of assisting the operator and verifying that the proper mixture is being prepared.

A three part label set consisting of Label Part 1, Label Part 2 and Label Part 3 provides a system for verifying that the proper base solution components are being used during the actual compounding operation. Label Part 1 is used by an operator during the compounding process and includes the patient's name, identification number and room number as well as the prescription bag number. The prescription itself in terms of final percent concentration is printed on Label Part 1 as well as the nutritional additives to be added to the bag after it is compounded. The nutritional additives may be specified on the label in terms of the dose and volume. Additionally, a base component section of Label Part 1 is provided to show the volumetric parameters (in milliliters) of the base solution as well as the solution codes, specific gravities and concentrations thereof.

Label Part 1 enables the operator to verify that the proper base solution containers 12 through 16 are mounted on the compounder 8 as well as verifying the concentrations of the base solutions. Further, as discussed below, the operator may compare each volume parameter shown

-20-

in milliliters in Label Part 1 to the quantities shown on the volumetric displays 70 through 74 of the compounder 8 that had been received from the host computer 4. The solution identification codes and specific gravities are also displayed on the display units 84 through 88 of the compounder 8. These additional displays provide an opportunity for the operator to further verify that the proper mixture is being prepared.

Label Part 2 is attached to the mixture bag 18 for identification and delivery purposes. This label contains the patient's name, identification number, room number and the prescription bag number. The prescription itself in terms of percent concentration and the total volume of the final mixture is also printed on Label Part 2. The nutritional additives to be added to the bag 18 after it is compounded are printed on the label in terms of dose. Blank lines are also provided on the label so that the operator can sign his name, the time and date of when the bag was compounded and the expiration time of the solution. The infusion rate is also included on Label Part 2. Label Part 3 contains detailed information of the mixture provided, including calorie content, and is designed for insertion into the patient's medical records.

After all of the mixture labels have been printed a Summary Label is prepared for all bags to be compounded from a given queue. The Summary Label provides information as to the total volume and concentration of each type of base solution and the number and size of mixture bags, such as bag 18, that will be needed.

After the labels have been printed in step 142, assuming the compounder 8 is available and is ready for receiving data, the operator depresses the AI key, 68a. The AI key signals the host computer 4 that the compounder 8 is ready to proceed. The host computer 4 transmits to the compounder 8 parameters defining the base solutions for the

-21-

first member of the queue to be compounded. The compounder 8 first displays the patient I/D code in the Displays 70-74, the bag I/D code in display 102 and three solution codes in the displays 84 through 88, respectively. If the patient I/D, bag I/D and solution codes match those present in the Label Part 1, the operator depresses the VI key switch 68b.

To insure that the operator does in fact verify that the displayed patient I/D, bag I/D and base solution codes match those of the corresponding pre-printed label, a delay of, for example, 5 seconds can be built into the control program in the ROM 112 of the compounder 8. A depression of the VI key switch 68b will not be responded to by the compounder 8 until said delay period has passed. Thus the operator must wait for at least the delay period before going on to the next step.

After a depression of the VI key switch has been sensed, the compounder 8 then transmits a verification code to the host computer 4. The host computer 4 then supplies base solution volumetric information to the compounder 8 which is displayed in the display units 70 through 74 as well as specific gravity information which is displayed in the units 84 through 88. Assuming the volume information shown in the displays 70 through 74 and the specific gravity information shown in the displays 84 through 88 matches the information on Label Part 1, the operator, after a delay period has elapsed, presses the Start key 100 which in turn starts the compounder 8.

The compounder 8, in step 146, then measures out the base solution volumes as described in the above referenced patents. To restart the compounder once the process has been completed the operator again depresses the AI key switch 68a. The host computer 4 continues to send sets of base solution parameters to the compounder 8 until the queue is empty.

-22-

In the event that the operator for some reason wishes to temporarily jump ahead to mix a bag which is further down in the queue, perhaps because of some emergency, the operator depresses the MI key switch 68c. The MI key switch alerts the compounder 8 to the fact that the operator wishes to manually enter a patient I/D code through the numeric pad of the key switches 62. Once the patient I/D code has been entered through the numeric pad of the key switches 62 the operator again presses the MI key switch 68c. The compounder 8 then transfers the patient identification code across the communications link 6 to the host computer 4.

When the host computer 4 has sensed the patient identification code, it searches forward in the queue looking for the corresponding set of parameters. It should be noted that only a search forward through the queue can be carried out. The prescription for a patient number corresponding to a prior member of the queue, will already have been compounded.

When the corresponding set of parameters or bag has been located in the queue, the host computer 4 then transmits base solution information to the compounder 8 which mixes the identified bag. Once this out of sequence compounding operation has been completed, the operator then depresses the AI key 68a which causes the host computer 4 to return to the prior location in the queue and to send the next member or set of parameters in the queue to the compounder 8.

It should be noted that after each set of parameters or bag has been sent to the compounder 8, the authorization flag for that particular bag is reset by the host computer 4. As a result, that particular prescription or set of parameters will have to be reauthorized to be compounded the next time the respective queue is sorted.

-23-

Additionally, in a step 148 an audit trail can be generated by the host computer 4. The audit trail can be printed on the printer 4C or simply stored on the disc 4B for later retrieval. The audit trail identifies at a given time what operation has taken place and by whom. For example, the audit trail records creation of and changes to patient files; authorizations of compounding, automatic and manual compounding; and the printing of labels.

In a preferred mode of operation the host computer 4 has at least two and preferably three operator authorization levels. The lowest level merely permits an operator to input prescription data through the display and data entry terminal 4a. The next level permits an authorized operator to change sets of parameters or bags in the data base on the disk drive 4b and to authorize the compounding of mixtures or prescriptions. In a third or maintenance level, prescriptions and other records can be deleted from the system.

Modification and variations of the present invention are possible in the light of the above teachings, for example, different sorting methods may be used. Bag parameters may be stored in groups not organized in queues and different display formats can be used all without departing from the spirit and scope of the present invention. Additionally, the host computer can be used to control a group of compounders or other devices essentially simultaneously. The host computer can also be used to generate accounting or management control reports based on the bags that have been compounded.

-24-

THAT WHICH IS CLAIMED IS:

1. A method of optimizing the compounding of a plurality of mixtures comprising the steps of:

providing a plurality of sets of parameters of mixtures to be compounded from a selected group of base solutions;

5 sorting the sets of parameters in accordance with the types of base solutions included in each said set; and compounding the mixtures in said sorted order thereby minimizing the needed quantity of base solution.

2. A method as defined in claim 1 including:

specifying parameters in a selected set as volumes to be added to the final mixture.

3. A method as defined in claim 2 including:

specifying parameters in a selected set alternately as a percent of the final mixture volume.

4. A method as defined in claim 3 including:

specifying parameters in a selected set alternately as a nutritional contribution to the final mixture.

5. A method as defined in claim 4 wherein:

the volumes, the percentages of the mixture volume and the nutritional contributions are three forms of a set of base solution parameters for a mixture and an unspecified form of base solution parameters may be determined from a specified form thereof.

6. A method as defined in claim 4 wherein:

changing one form of a set of base solution parameters produces a corresponding change in the alternate forms of said set of parameters.

7. A method as defined in claim 2 including:

prestoring standard combinations of base solution parameters for later use;

determining when a selected mixture includes a prestored standard combination of parameters; and

-25-

providing the corresponding prestored combination of parameters as at least part of the set of parameters for the corresponding select mixture.

8. A method as defined in claim 1 including:
authorizing selected sets of parameters for compounding;

5 providing an indication for each set of authorized parameters and sorting only authorized sets of parameters.

9. A method as defined in claim 4 including:
transmitting volume parameters of base solutions corresponding to an authorized set of parameters from a storage location to a compounding location to form the
5 selected mixture.

10. A method as defined in claim 4 including the steps of:

forming groups of parameters; and
compounding each corresponding group of mixtures
5 in a predetermined time interval.

11. A method as defined in claim 10 including forming each group of parameters as a queue.

12. A method as defined in claim 4 including printing an ordered sequence of labels corresponding to the sorted sequence of parameters in a selected group.

13. A method as defined in claim 12 including:
forming the sorted sets of parameters into a queue having a corresponding sorted order; and

5 forming a print queue for labels having a corresponding sorted order.

14. A method as defined in claim 10 including:
providing an authorizing indicia for each group of parameters; and

5 checking each indicia to determine if compounding of said corresponding mixture has been authorized.

-26-

15. A method as defined in claim 4 including forming a plurality of queues wherein sets of parameters are stored as members of a selected queue; and

sorting the members of a selected queue.

16. A method as defined in claim 15 including:

providing an operator settable authorization indicia for each member of a queue; and

5 sorting only queue members which have said authorization indicia set to a selected condition.

17. A method as defined in claim 16 including a second sorting step wherein authorized members of a queue are further sorted in accordance with the specified concentrations of corresponding base solutions.

18. A method as defined in claim 14 including:

logging selected operations to form an audit trail.

19. A system for optimizing the compounding of a plurality of mixtures comprising:

5 means for storing a plurality of sets of parameters of mixtures to be compounded from a selected group of base solutions;

means for sorting said sets of parameters in accordance with the types of base solutions included in each said set; and

10 means for mixing the base solutions in said sorted order thereby minimizing the required quantity of base solution.

20. A system as defined in claim 19 including control means for storing parameters of a selected mixture in the form of a volume to be added to said mixture.

21. A system as defined in claim 20 wherein said control means include means for storing the parameters of a selected mixture alternately as a percent of the final mixture volume.

-27-

22. A system as defined in claim 21 wherein said control means include means for storing the parameters of a selected mixture alternately as a nutritional contribution to the final mixture.

23. A system as defined in claim 22 wherein said control means include means for determining unspecified volumes, percentages of the mixture volume or the nutritional contributions from a specified form thereof.

24. A system as defined in claim 23 wherein said control means include means for changing a selected form of a set of parameters and means for making a corresponding change in the alternate forms of said set of parameters.

25. A system as defined in claim 20 including:

means for prestoring standard combinations of parameters;

5 means for identifying a said prestored standard combination to be included in a selected set; and

means for including said prestored combination parameters in said set.

26. A system as defined in claim 19 including:

means for authorizing selected sets of parameters for compounding;

5 means for providing an indication for each said authorized set of parameters;

and means for sorting only authorized sets of parameters.

27. A system as defined in claim 26 including:

means for transmitting volume parameters of base solutions corresponding to an authorized set of parameters from said storage means to said compounding means to form
5 the selected mixture.

28. A system as defined in claim 26 including:

means for forming groups of sets of parameters of mixtures; and

-28-

5 means for compounding each authorized member of a corresponding selected group in a predetermined time interval.

29. A system as defined in claim 28 wherein said means for forming groups include queueing means for forming each group as a queue.

30. A system as defined in claim 29 including means for sorting selected queue members.

31. A system as defined in claim 30 including means for printing an ordered sequence of labels corresponding to the sorted sequence of members in a selected queue.

32. A system as defined in claim 26 including means for forming a queue of sets of authorized parameters having a corresponding sorted order; and including means for forming a print queue for labels having a corresponding sorted
5 order.

33. A system as defined in claim 32 including:
means for setting an authorizing indicia for each member in a selected queue to a predetermined state; and
means for checking each said indicia to determine
5 if said corresponding indicia has been set to said state.

34. A system as defined in claim 24 including:
means for forming a plurality of queues wherein sets of parameters are stored as members of a selected queue; and
5 means for sorting said members of said selected queue.

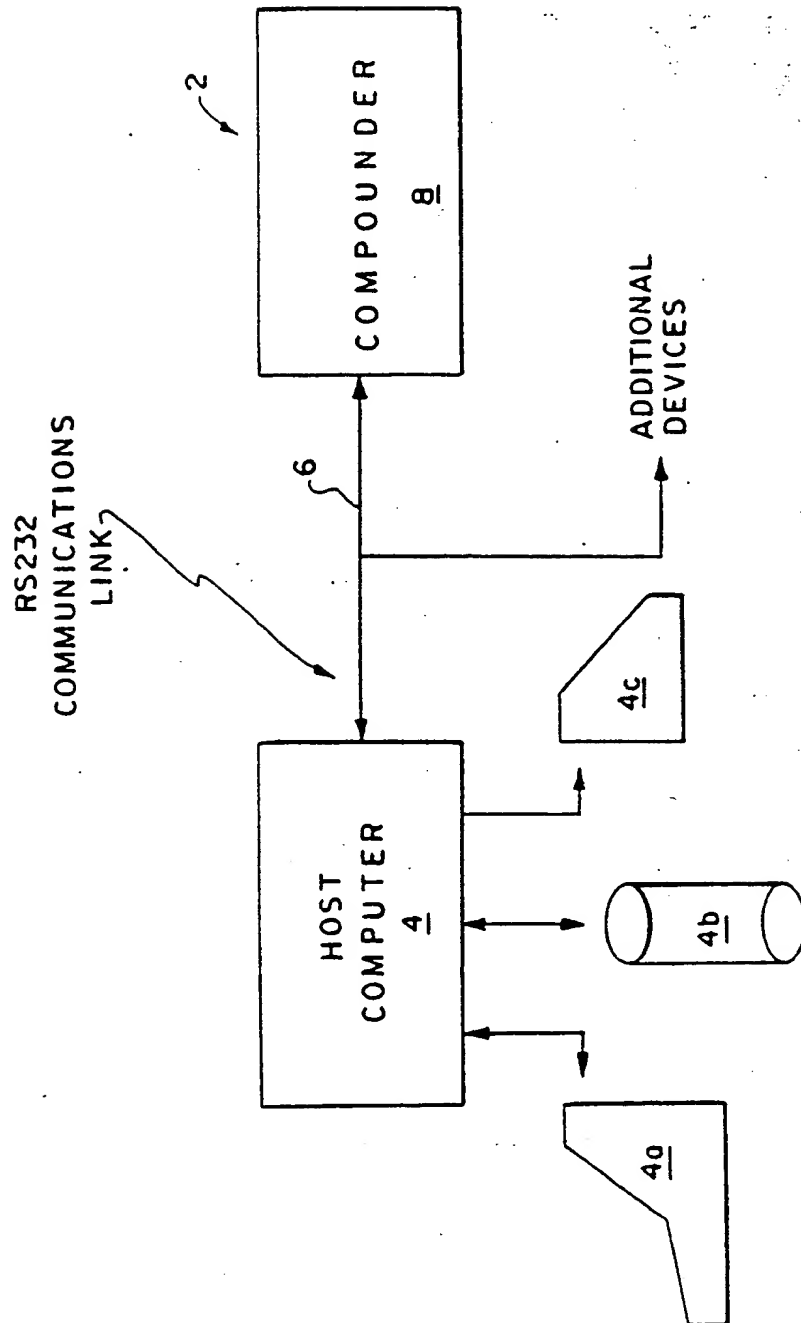
35. A system as defined in claim 29 including:
means for authorizing selected members of a selected queue; and

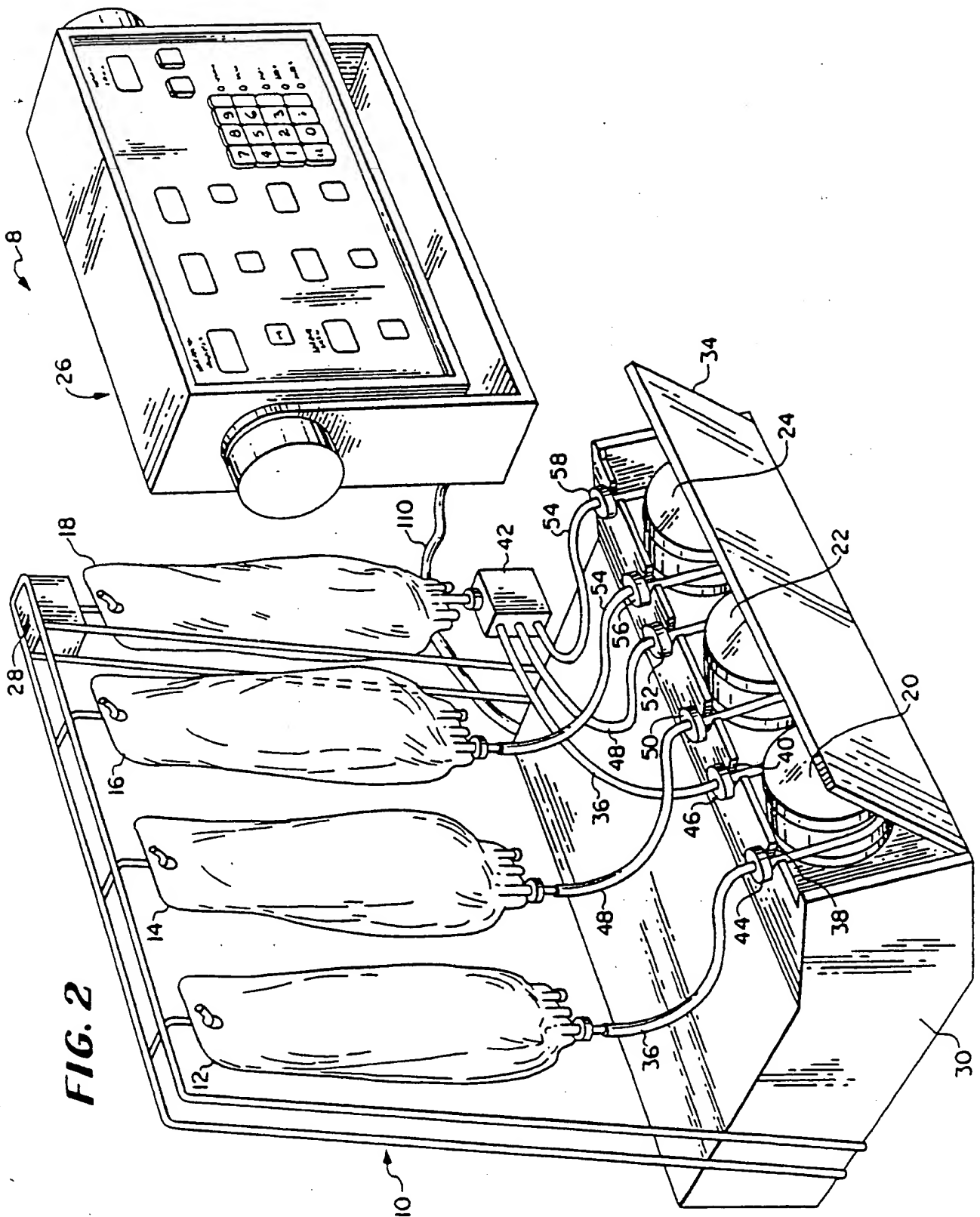
means for sorting only authorized queue members.

36. A system as defined in claim 35 including further means for sorting in accordance with the specified concentrations of corresponding base solutions.

1/4

FIG. 1





3 / 4

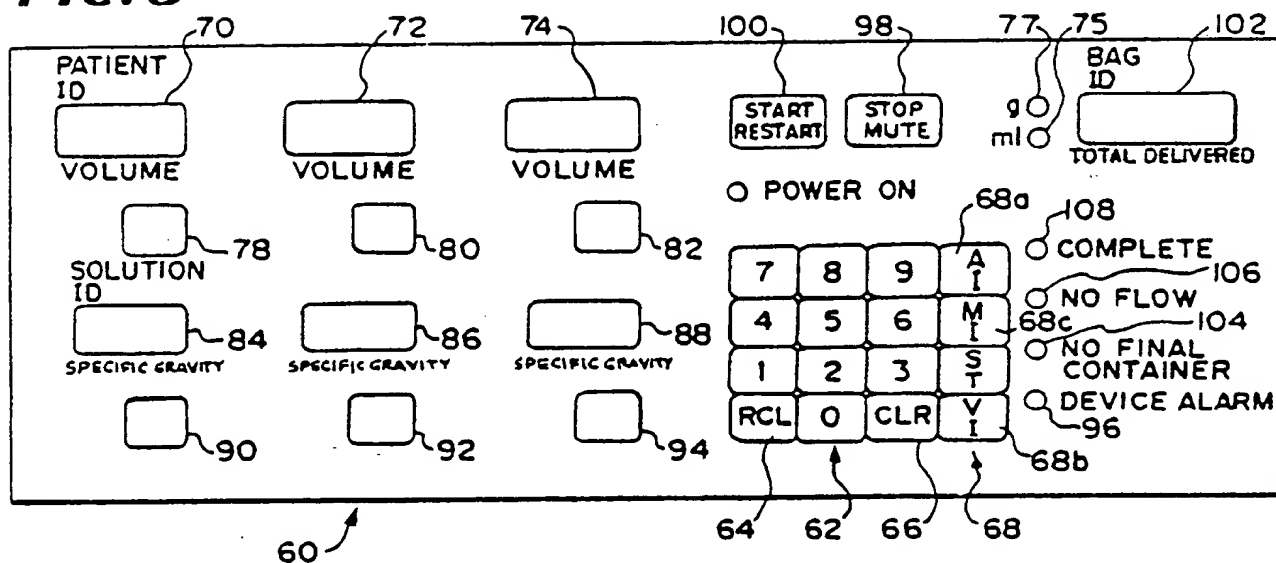
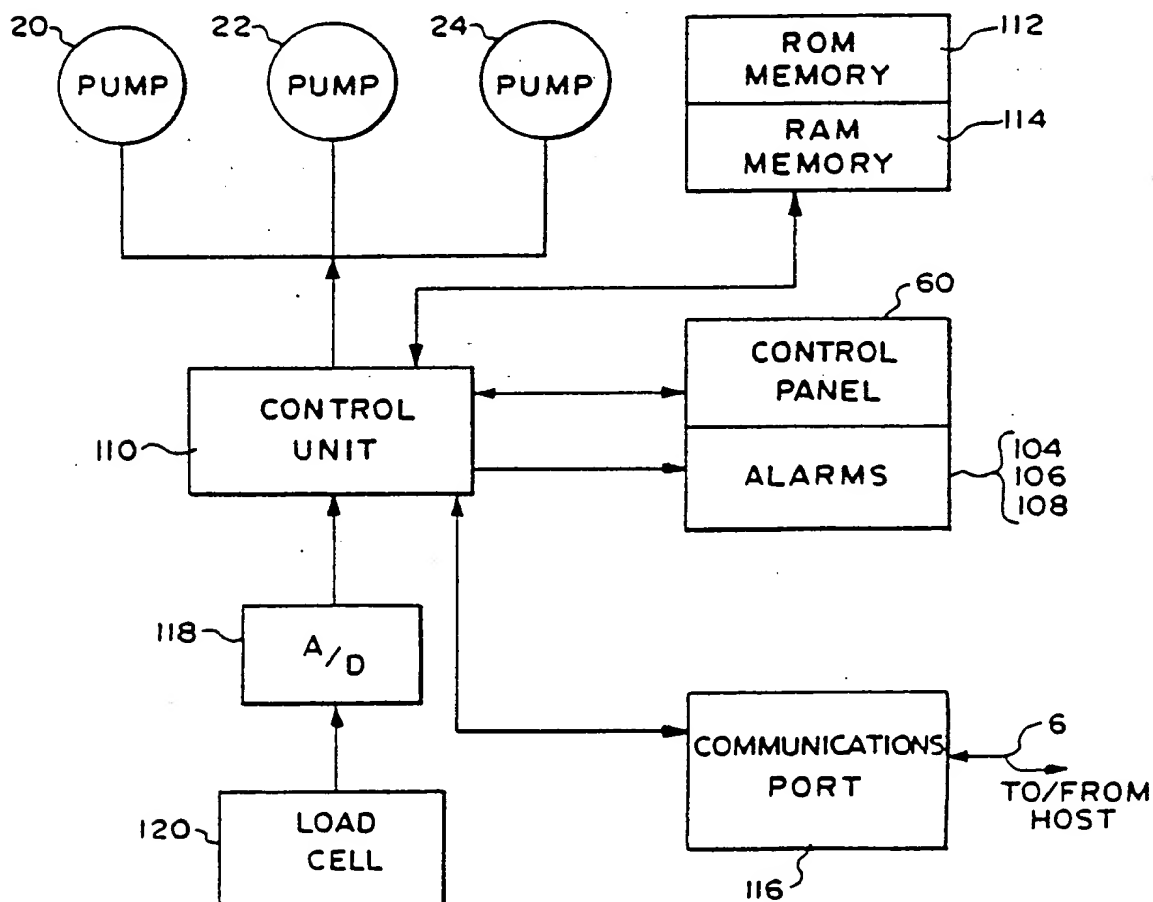
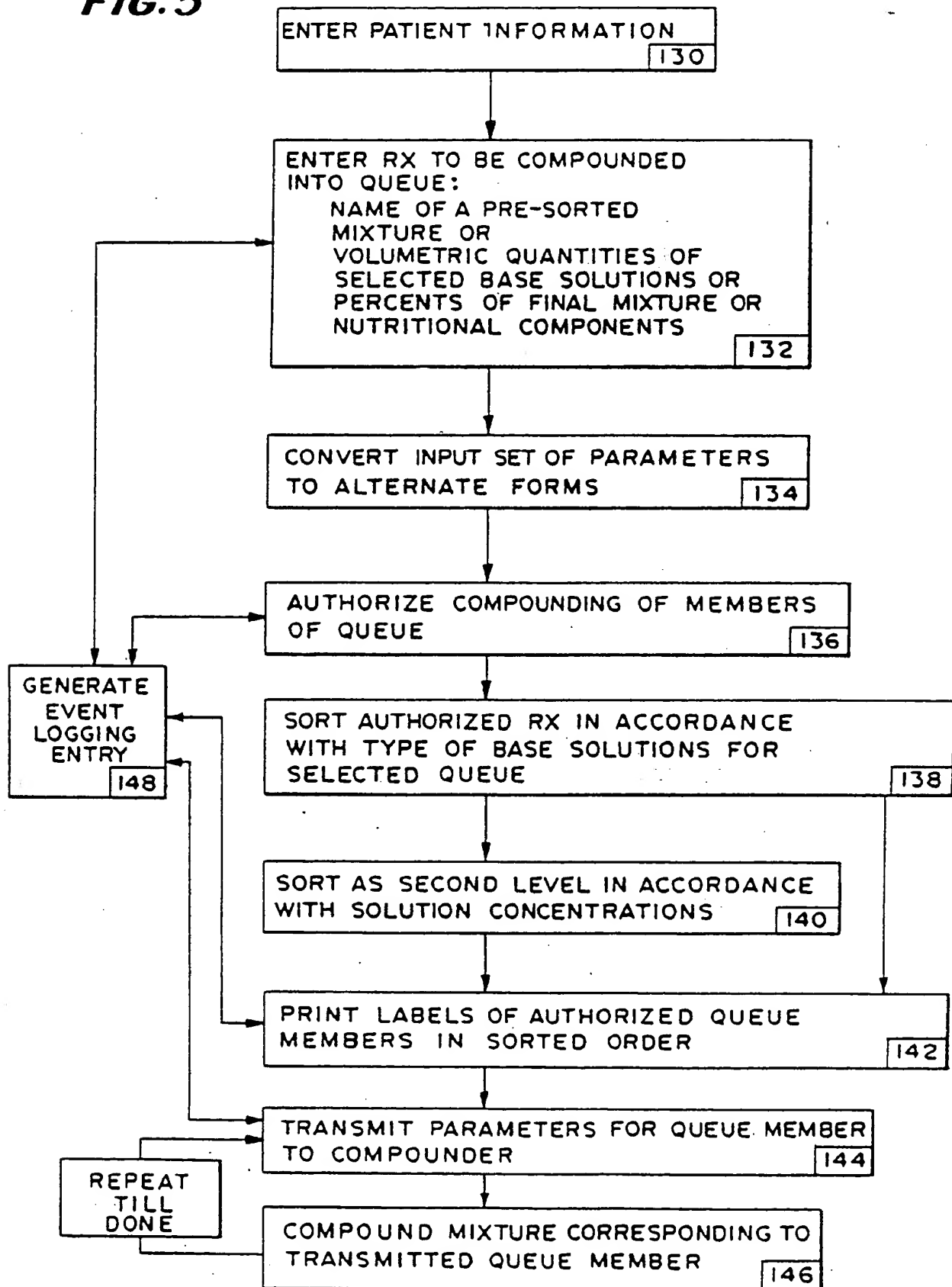
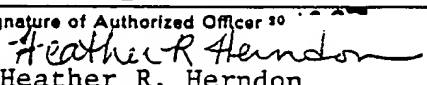
FIG. 3**FIG. 4**

FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No PCT/US85/02025

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹		
According to International Patent Classification (IPC) or to both National Classification and IPC		
INT. CL. B67d 5/14 G06F 15/42 G06F 15/46		
U.S. CL. 222/2, 364/148, 502		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
U.S.	364/148, 152, 502 141/1, 83 222/2, 52, 132, 134, 136	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
Y	US, A, 3,670,923, Hawes, Jr. et al 20 June 1972	1-36
A	US, A, 3,904,079, Kross 09 September 1975	1-36
A	US, A, 4,333,356, Bartels et al. 08 Jun. 1982	1-36
Y, P	US, A, 4,527,245, Axelson, Jr. et al., 02 July 1985	1-36
A, P	US, A, 4,545,008, Sominin et al., 01 October 1985	1-36
A	US, A, 4,473,884, Behl 25 September 1984	1-36
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁵ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ¹		Date of Mailing of this International Search Report ²
15 January 1986		22 JAN 1986
International Searching Authority ³		Signature of Authorized Officer ²⁰
ISA/US		 Heather R. Herndon

THIS PAGE BLANK (USPTO)